May 20, 2021

Kensey Nash Corp.
Robin M. Fatzinger
Regulatory Affairs Specialist
735 Pennsylvania Drive
Exton, Pennsylvania 19341

Re: K073519
Trade/Device Name: QuickCat Extraction Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ

Dear Robin M. Fatzinger:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated March 28, 2008. Specifically, FDA is updating this SE Letter as an administrative correction because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2021.05.20 10:08:07 -04'00'

Gregory O'Connell
Assistant Director
Plaque Modification Devices Team
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 8 2008

Kensey Nash Corp.
c/o Ms. Robin M. Fatzinger, RAC
Vice President of Clinical and Regulatory Affairs
735 Pennsylvania Drive
Exton, PA 19341

Re: K073519
Quickcat Extraction Catheter, Model 60090-01
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II (two)
Product Code: DXE
Dated: March 3, 2008
Received: March 4, 2008

Dear Ms. Fatzinger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K 073519

Device Name: **QuickCat™ Extraction Catheter**

Indications for Use:

The QuickCat™ Extraction Catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the arterial system.

Prescription Use: **X**
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K073519

510(k) Summary

MAR 2 8 2008

510(k) Number: K073519

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR§807.92.

Submitted By: Kensey Nash Corporation
735 Pennsylvania Drive
Exton, PA 19341 USA

Contact Person: Cindy R. Varughese, RAC
Regulatory Affairs Specialist
Tel: (484) 713-2100
Fax: (484) 713-2903
E-mail: Cindy.Varughese@kenseynash.com

Trade Name:	QuickCat™ Extraction Catheter
Common Name:	Embolectomy Catheter
Classification Name:	Embolectomy Catheter *(21 CFR Section 870.5150)*
Regulatory Class:	Class II
Device Product Code:	DXE
Predicate Device:	Kensey Nash Corporation's QuickCat™ Extraction Catheter (K060092)
Date Prepared:	December 12, 2007

Description of Device:
The QuickCat™ Extraction Catheter is a single use, disposable, dual lumen catheter with associated accessories consisting of a 30 ml. vacuum syringe, extension tubing with stopcock, and an independent 40-micron filter basket. The 145 cm working length and is compatible with 6F guiding catheters with an inner diameter (I.D.) $\geq$ 0.068" (1.73 mm) and 0.014" (0.36 mm) diameter guidewires. The extraction lumen of the catheter facilitates removal of emboli and thrombi via the attached tubing assembly, stopcock and vacuum syringe. The atraumatic distal tip, which incorporates a radiopaque marker for visibility under fluoroscopy, provides for smooth passage in the arterial system. The catheter consists of three segments. The stiffer proximal segment and more flexible distal segments provide the required structural integrity and flexibility to navigate tortuous vasculature. The distal segment consists of a dual lumen to allow for "rapid exchange" attachment to the guidewire. The catheter's distal portion has a hydrophilic coating to enhance deliverability. A 40-micron pore filter basket is supplied to assist in filtering of blood and thrombotic material for visual or laboratory analysis.

Intended Use:
The QuickCat™ Extraction Catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the arterial system.

Substantial Equivalence:
QuickCat is substantially equivalent to the predicate device with regard to intended use, principles of operation, and technological characteristics.

Non-Clinical Summary:
Non-clinical verification has been verified through *in-vitro* bench testing and biocompatibility testing. Results of this testing indicate that the QuickCat design meets all specifications and intended use.